DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Taiwan AN I Co., LTD
c/o Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
13 Red Fox Lane
Littleton, Colorado 80127

Re: K052586
Trade/Device Name: A & I Pediatric Wheelchairs
Model No. RWAL2006-12
Model No. LT3207-12
Model No. LT3211-12
Model No. LT3207-14
Model No. LT3211-14

A & I Bariatric Wheelchairs
Model No. WCDE2611P
Model No. WCDE2811P
Model No. WCDE3011P
Model No. WCDS2607P
Model No. WCDS2807P
Model No. WCDS
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: October 5, 2005
Received: October 5, 2005

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your device and thus, permits your devices to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052586

Device Name:

A & I Pediatric Wheelchairs
Model No. RWAL2006-12
Model No. LT3207-12
Model No. LT3211-12
Model No. LT3207-14
Model No. LT3211-14

A & I Bariatric Wheelchairs
Model No. WCDE2611P
Model No. WCDE2811P
Model No. WCDE3011P
Model No. WCDS2607P
Model No. WCDS2807P
Model No. WCDS3007P

Indications for Use:

The A&I Pediatric Wheelchairs are intended to provide mobility to persons, primarily children, who may be limited to a sitting position.

The A&I Bariatric Wheelchairs are intended to provide mobility to persons, primarily larger adults, who may be limited to a sitting position.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052586